510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K050236

B. Purpose for Submission:

Addition of fluorescent in-situ hybridization (FISH) imaging to the BANDView System

C. Manufacturer and Instrument Name:

Applied Spectral Imaging, Ltd., FISHView

D. Type of Test or Tests Performed:

N/A

E. System Descriptions:

1. Device Description:

   The FISHView System is an integrated digital platform constructed of a microscope, camera, frame grabber and a workstation. It is designed to acquire images of cells and enables identification and examination of cells of interest. Cytological analysis experts can view, manually scan cells and record the image, using both bright field and fluorescent illumination. The acquired images can be enhanced, archived, retrieved and printed. The digital visualization, processing, and storage of FISH multi dye images of the FISHView System are additions to the legally marketed BANDView System.

2. Principles of Operation:

   Microscopic slides are prepared using standardized cell preparation methods. The user interactively controls the microscope under brightfield or fluorescent illumination. Each field of view is visualized using several fluorescent filters. The device generates and displays a single layer or a combined image for each field of view. The work station is software controlled and includes features such as: acquisition of images, views, editing relocation, image enhancement, manual counting and classification, printing, export of images and backups. This methodology is well established and has been used in other cleared devices.

3. Modes of Operation:

The FISHView system is manually operated. The user has interactive control over the scan of the slide under either bright field or fluorescent illumination.

4. Specimen Identification:

   Patient name and individual specimen slide case details are entered in the Case Data Manager.

5. Specimen Sampling and Handling:

   Standardized cell preparations of amniotic fluid, chorionic villus, peripheral blood, bone marrow and solid tumor are applied to microscope slides.

6. Calibration:

   N/A

7. Quality Control:

   No special quality control is required; however annually preventive maintenance by ASI service personnel is recommended.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___x____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5260, Automated cell-locating device

2. Classification:

   Class II

3 Product code:

   LNJ, Analyzer, Chromosome, Automated

4. Panel:

   88 (Pathology)

G. Intended Use:

1. Indication(s) for Use:

   The FISHView System is intended to be used for karyotyping with real-time microscope images from cultured and stained cell specimens in their metaphase. The system works with bright field and fluorescent samples. Specimens suitable for banding analysis are: amniotic fluid, peripheral blood, chorionic villus, bone marrow and solid tumor. Karyotyping is normally applied for the pre and postnatal diagnosis of birth defects, chromosome abnormalities, genetic diseases (such as Down's Syndrome), cancer, and for the follow up of cancer treatment. The FISHView system does not locate metaphase spreads; it does not rank the given cells according to quality; nor does it automatically classify chromosomes.

   In addition the FISHView is intended as an aiding tool to the pathologist or cytogeneticist for digital visualizing, processing, counting and classification of stained cells and for storage of FISH multi-dye images of the following specimens: amniotic fluid, peripheral blood, chorionic villus, bone marrow and solid tumor.

   The FISHView system does require and relies on the operator to analyze the digitized microscope images.

2. Special Conditions for Use Statement(s):

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   BANDView System (k012103)

   BioView, Ltd., Duet™ System (k040591)

2. Comparison with Predicate Device:

Similarities			
Item	Device	BANDView	Duet
Cell Source	Amniotic fluid, chorionic villus, bone marrow, peripheral blood and solid tumor	Amniotic fluid, chorionic villus, bone marrow, peripheral blood and solid tumor	Peripheral blood, bone marrow, and amniotic fluid
Preparation techniques	Same	Same	Same

Similarities			
Item	Device	BANDView	Duet
Hardware	Same	Same	Same

Differences			
Item	Device	BANDView	Duet
Automated scanning	No	No	Yes
Spatial Resolution	1280 x 1024	1280 x 1024	640 x 480

I. Special Control/Guidance Document Referenced (if applicable):

N/A

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

N/A

b. Precision/Reproducibility:

N/A

c. Linearity:

N/A

d. Carryover:

N/A

e. Interfering Substances:

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

A comparison study was performed between the FISHView System and routine examination of the same cells directly through the microscope. The evaluation was performed with a total of 115 slides from different specimens (amniotic fluid,

blood lymphocytes, chorionic villus, bone marrow, and solid tumors) using various DNA probes by 2 expert cytogeneticists. The following parameters were compared between the two methods: image quality, number of FISH signals, clinical adequacy, data loss, image alteration, and safety problems. The cytogeneticists either approved or disapproved each of these parameters for each specimen type and accompanying DNA probe. No parameters were disapproved for the FISHView System.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.